The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRED S. LAMB

Appeal No. 2006-2342
Application No. 09/512,926

ON BRIEF

Before MILLS, GREEN, and LEBOVITZ, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 6-11, 23 and 25. Claims 1 and 25 are representative of the claims on appeal, and read as follows:

1. A method to normalize the contractile response of vasculature in a patient in need of such normalization, the vasculature comprising a vascular smooth muscle layer and a compromised endothelial cell layer, wherein the method comprises administering a pharmaceutically effective amount of a CLC3 blocker, or a pharmaceutically acceptable salt thereof.

25. A method to normalize the contractile response of a vasculature in response to a vasoconstrictor agonist in a patient in need of such normalization, the vasculature comprising a vascular smooth muscle cell layer and a

compromised endothelial cell layer, wherein the method comprises administering a pharmaceutically effective amount of a CLC3 blocker, or a pharmaceutically acceptable salt thereof, and wherein the vasoconstrictor agonist is norepinephrine.

The examiner relies upon the following references:

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|---|---|---|---|
| Stromberg | | 5,470,883 | Nov. 28, 1995 |
| Grainger et al. (Grainger) | US | 6,197,789 B1 | Mar. 06, 2001 |

Claims 1, 6-11 and 23 stand rejected under 35 U.S.C. § 103(a) as being obvious over Grainger. In addition, claim 25 stands rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Grainger and Stromberg. After careful review of the record and consideration of the issues before us, we affirm the rejection of claims 1, 6-11 and 23, but reverse the rejection of claim 25.

## BACKGROUND

According to the specification, "[v]ascular smooth muscle can be damaged by mechanical or physiological means," and that "[m]edical procedures, such as balloon angioplasty, disease-induced or genetically-influenced pathoogies, [sic] such as diabetes and hypertension, create risk or predisposal for endothelial damage." Id. at 3.

The present invention "provides methods to reduce the sensitivity of endothelially-compromised vascular smooth muscle" through the administration of a CLC3 blocker. Id. Tamoxifen is a preferred CLC3 blocker. See id. at 5.

## DISCUSSION

Claims 1, 6-11 and 23 stand rejected under 35 U.S.C. § 103(a) as being obvious over Grainger. As appellants do not argue the claims separately, we focus our analysis on independent claim 1. See In re Dance, 160 F.3d 1339, 1340 n.2, 48 USPQ2d 1635, 1636 n.2 (Fed. Cir. 1998) (noting that dependent claims not argued separately on the merits rise or fall with the independent claim to which they relate).

Grainger is cited for teaching that "tamoxifen is useful on vascular smooth muscle cells to inhibit the pathological activity of the smooth muscle cells, and to inhibit the activation of endothelial cells associated with vascular surgery, diabetes, hypertension, and coronary artery blockage." Examiner's Answer, page 3 (emphasis removed). Moreover, according to the examiner, Grainger teaches that "procedural vascular traumas including surgical procedures include vascular surgery (e.g. angioplasty, coronary bypass) and the pathologies (atherosclerosis, myocardial infraction [sic] and stroke) can be prevented by the administration of tamoxifen." Id. (emphasis removed).

The examiner contends that Grainger does not "expressly teach the normalization of contractile response set forth in claim 1," but concludes:

> It would have been obvious to one of ordinary skill in the art to modify the teaching of Grainger [ ] and employ tamoxifen to normalize the contractile response of vasculature in Grainger [ ] patients since the teaching of "inhibiting contraction" encompasses the "normalization" since the effect of inhibiting contraction encompasses the "normalization" since the effect of inhibition of

> the contraction of vascular smooth muscle would "normalize" the contraction of the patients disclosed by Grainger [ ].

Id.

We find that in fact Grainger anticipates claim 1, and thus affirm the rejection of claims 1, 6-11 and 23 over Grainger, although our reasoning differs from that of the examiner. As noted by the Court of Appeal for the Federal Circuit,

> "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As this court's predecessor stated in In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirg v. Kemmer, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 USPQ 665, 667 (1939)) (internal citations omitted):
>
> > Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.
>
> Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See In re Oelich, 666 F.2d at 581; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 60, 2 USPQ2d 1051, 053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See In re King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of

> those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id., 801 F.2d at 1326.

MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999); see also Bristol-Myers Squibb Co. v. Ben Venue Laboratories, 246 F.3d 1368, 1376, 58 USPQ2d 1508, 1514 (Fed. Cir. 2001) (stating in the context of a claimed process that was drawn to the same use comprising the same steps of the prior art, "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.").

Claim 1 requires administering a pharmaceutically effective amount[1] of a CLC3 blocker, such as tamoxifen, to a patient who has had a surgical procedure[2] (see, e.g., claim 8).

Grainger teaches the administration of tamoxifen, a CLC3 blocker, to a patient who has had a surgical procedure, such as coronary angioplasty, see Abstract and Col. 1, lines 24-38, and in fact teaches a kit comprising a catheter, a stent, and/or a shunt "and a unit dosage form of an amount of a compound of formula (I) and/or tamoxifen effective to accomplish these therapeutic results," id. at Col. 5, lines 33-49. A "compromised endothelial cell layer" would occur as a result of surgery. See Specification, page 14.

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[1] The specification defines "effective amount" as the dosage of active compound "sufficient to provide therapeutic treatment of the specified medical indication." See id. at 14.

[2] "Surgical procedure" is defined by the specification as "any medical procedure requiring mechanical or mechanical/chemical manipulation of a patient's body, wherein said procedure results in damage to the endothelium layer adjoining vascular smooth muscle." Id. at 14.

The fact that Grainger teaches that the tamoxifen is administered to a patient for inhibiting smooth muscle proliferation, see abstract, is irrelevant, as instant claim 1 requires the administration of the same compound, i.e., tamoxifen, to the same group of patients, i.e., patients who have undergone a surgical procedure. That tamoxifen may also normalize the contractile response of the vasculature would be an inherent property of the method, and its specific recitation in the claim does not render the method of claim 1 patentable.

Appellant argues that "[t]he Grainger [ ] patent does not, however, teach or suggest normalizing the contractile response of endothelially-compromised vascular smooth muscle." Appeal Brief, page 3. But, as noted above, Grainger teaches the administration of tamoxifin, a CLC3 blocker, to patients who have undergone vascular surgery, and thus teaches the administration of the same compound as required by claim 1 in a pharmaceutically effective amount to the same group of patients. The normalization of the contractile response of endothelially-compromised vascular smooth muscle is an inherent result of the process, and the recitation of that new result of an old process does not render that process patentable. See In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) ("It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.").

Claim 25 stands rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Grainger and Stromberg.

Grainger is relied upon as in the previous rejection. See Examiner's Answer, page 4. According to the examiner, Grainger does not teach that norepinephrine causes the contractile response of the vasculature as set forth in claim 25. See id.

Stromberg is cited for teaching "a method of inhibiting or reversing the peripheral vasoconstrictive effect of norepinephrine set forth by Applicants claim [sic]25 by the oral administration of tamoxifen citrate." See id.

The examiner concludes:

> It would have been obvious to one of ordinary skill in the art to employ tamoxifen to normalize the contractile response of vasculature comprising a vascular smooth muscle cell layer and a compromised endothelial cell layer caused by norepinephrine because Stromberg teaches tamoxifen is useful for reversing (normalizing) the vasoconstictive effect of norepinephrine and because Grainger [ ] teach[es] that tamoxifen is useful for inappropriate or pathological activity of vascular smooth muscle cells and endothelial cells. One would have been motivated to employ tamoxifen to reverse (normalize) the contractile response of norepinephrine to achieve inhibition of contraction of vasculature caused by norepinephrine and to treat inappropriate or pathological activity of vascular smooth muscle cells or endothelial cells as taught by Grainger [ ].

Id. at 5.

"[T]he Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (citation omitted). An adequate

showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000).

As discussed above, Grainger teaches a method of inhibiting smooth muscle proliferation in a patient who has hypertension, diabetes, or who has had vascular surgery, through the administration of tamoxifen or its structural analogs. See id., abstract, Col. 7, lines 15-32, and Col. 24, line 47-Col. 25, line 8. Stromberg, however, is drawn to a method of blocking or reversing vasoconstriction of an intentionally or unintentionally administered adrenergic agent such as norepinephrine. See id. at Col. 2, lines 6-16. Thus, although both Grainger and Stromberg teach the administration of tamoxifen, they teach it for different purposes to different patient populations. We conclude therefore that there is no motivation to combine Grainger and Stromberg, and are thus compelled to reverse the rejection of claim 25 over their combination.

## SUMMARY

We reverse the rejection of claim 25 under 35 U.S.C. § 103(a), but affirm the examiner's rejection of claims 1, 6-11 and 23. Since our reasoning with respect to the rejection differs from that of the examiner, however, we designate our affirmance of that rejection as a new ground of rejection under 37 CFR § 41.50(b). See In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976).

## TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED-IN-PART; REVERSED-IN-PART; 37 CFR § 41.50(b)

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